UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: Levaquin Products Liability Litigation,	File No. 08-md-1943 (JRT/AJB)
	Minneapolis, Minnesota November 3, 2010 2:25 P.M.

BEFORE THE **HONORABLE JOHN R. TUNHEIM**
UNITED STATES DISTRICT COURT JUDGE
(MOTIONS HEARING)

APPEARANCES

For the Plaintiffs: **RONALD S. GOLDSER, ESQ.**
LEWIS J. SAUL, ESQ.
BRIAN McCORMICK, ESQ.
CHRIS PINEDO, ESQ.

For the Defendants: **JOHN DAMES, ESQ.**
WILLIAM H. ROBINSON, JR., ESQ.
TRACY J. VAN STEENBURGH, ESQ.
WILLIAM ESSIG, ESQ.

Court Reporter: **KRISTINE MOUSSEAU, CRR-RPR**
1005 United States Courthouse
300 Fourth Street South
Minneapolis, Minnesota 55415
(612) 664-5106

Proceedings recorded by mechanical stenography; transcript produced by computer.

2:25 P.M.

(In open court.)

THE COURT: You may be seated. Good afternoon, everyone. This is MDL number 08-1943, In Re: Levaquin Products Liability Litigation and Schedin versus Johnson & Johnson, et al, number 08-5743.

Counsel, note appearances first for the plaintiffs.

MR. GOLDSER: Good afternoon, Your Honor. Ron Goldser for the plaintiffs. I have a new face for you today, Mr. Chris Pinedo from Corpus Christi, Texas. He is associated with Mikal Watts.

THE COURT: Very well.

MR. SAUL: Good afternoon, Your Honor. Lewis Saul for plaintiffs.

MR. FITZGERALD: Good afternoon, Your Honor. Kevin Fitzgerald for plaintiffs.

THE COURT: Good afternoon to all of you.

MR. DAMES: Good afternoon, Your Honor. John Dames for the defendants.

MR. ROBINSON: Good afternoon, Your Honor. Bill Robinson for defendants.

MS. VAN STEENBURGH: Tracy Van Steenburgh for defendants, Your Honor.

MR. ESSIG: Bill Essig for the defendants.

THE COURT: Good afternoon to all of you. We have a pretrial conference today and a number of matters to go over. I see we have an agenda. I have it here someplace.

Mr. Goldser, do you want to begin?

MR. GOLDSER: Thank you, Your Honor. With the Court's permission, we thought we would take some of the procedural matters associated with the trial first and leave the motion arguments for the end of the agenda, and although we have a listing of them, they're not entirely in perfect order, so again with your permission, I would like to bounce around a little bit.

THE COURT: Sure.

MR. GOLDSER: I thought I would take things up in the sequence of trial. So if we start at the beginning of trial, the place to start is jury questionnaire and voir dire. As you will hear from many of these items, we need the Court's feedback and your assistance in helping us to get through some of these in the phases that we're in.

With regard to the questionnaire, you may recall that we had submitted a proposed questionnaire to the Court. That questionnaire had three parts to it, a set of agreed questions for the questionnaire, defendants' proposed questions and plaintiffs' proposed questions.

THE COURT: For which there is objections?

MR. GOLDSER: Yes, indeed. We object to the defendants' proposed questions. The defense objects to plaintiffs' proposed questions. We need your feedback in a couple of arenas: A, which questions are going to be appropriate; B, of those questions that are not on the questionnaire, which of them are voir dire questions.

You may recall that pretrial order number nine had a deadline of this past Monday for voir dire questions. Ms. Van Steenburgh and I spoke about that, and we agreed that what you do with the jury questionnaire will have some impact on whether there are additional questions for voir dire or not and if so how we do that.

And, C, when does the jury questionnaire get sent out, and we also have a disagreement among the parties about that. We would prefer to have the jury questionnaire sent out as soon as possible so that we can start getting completed questionnaires back from prospective jurors early. That will give us some time to evaluate them, make strike requests at the beginning of the jury selection process so that we don't through a voir dire process and then have to strike people.

We can impanel people who at least pass the first cut, and I will let defense speak for themselves, but they would prefer to do it on the morning of the trial and evaluate them on the morning of the trial. So those are

the issues surrounding jury questionnaire, voir dire. Your assistance in helping us decide what are the questions that go in one and not the other would be greatly appreciated, and I will leave it to defense on those issues at this point.

THE COURT: Ms. Van Steenburgh?

MS. VAN STEENBURGH: Thank you, Your Honor. There isn't really much to say about the jury questionnaire in terms of, you know, it will be up to you in terms of what questions you do want to go onto the questionnaire.

Whether some of those will turn into voir dire questions, I guess I hadn't really thought about that. The voir dire that I had in mind or we were talking more about was if there might be answers to some of the jury questionnaire questions that might need follow-up or follow on, and we really won't know that maybe until we see some of those answers. There might be follow-up questions that we would want you to ask depending on how they answered that.

With respect to when that is sent out or if it is sent out at all, the world is changing, and it's interesting. I have been involved in trials where we have sent out the questionnaire early. I have never seen it where we have struck a witness just based on a questionnaire. We have impaneled everybody and then asked

follow-up questions.

The more important question is, everybody has access to the Internet these days, and I think the danger with a jury questionnaire that gets sent out too soon is, it's kind of like somebody explained to me. If you say to someone don't think about the word "rat" for the rest of the day, they cannot help it. There is some temptation, and there has been some literature out there that prospective jurors cannot help themselves, and they will go do research.

Even if you admonish them and tell them not to do it, they will. They just can't help it, and they will Google names of lawyers and companies and plaintiffs and everything else, and so then they come in predisposed, and you have some issues. So we think it would be a better practice in order to avoid that to have the questionnaire provided to the jury when they come in.

We have tried to keep it short so that it would be maybe no more than an hour, and then people can compile the information fairly quickly, and then we can impanel prospective jurors and go from there.

THE COURT: How long do you think that would take? I'm just asking the question.

MS. VAN STEENBURGH: Yeah, I know.

THE COURT: I've used jury questionnaires maybe

twice. In a typical case I won't use them. I think it's appropriate in this case. I will obviously permit its use. If we didn't give it to them until Monday morning and they have got 45 minutes or so of orientation that they have to go through --

What time are they supposed to arrive, Janet?

THE CLERK: Nine o'clock.

THE COURT: So --

MS. VAN STEENBURGH: Well, there are two thoughts that we've had on that. One is, they come in, do the orientation, get the questionnaire. It takes about an hour. Then it will take us about an hour maybe to go through them, so that will take most of the morning. Depending on how quickly you do voir dire, we can get them impaneled midafternoon and maybe do openings by the end of the first day, or the openings would be started the next day.

THE COURT: With the information on the questionnaire, I mean, I think we can go through it much more quickly. Obviously there will be follow-up questions based on answers to the questionnaire, but some of the basics get out of the way.

MS. VAN STEENBURGH: Right. So that's kind of what we're thinking about at this point in time.

THE COURT: Mr. Goldser?

MR. GOLDSER: A couple of things. The longer the questionnaire, the shorter the voir dire. So you can, if you do send it out early, you can get as much time utilized most efficiently by doing this out of court. We have a rule around our office that goes, twice as long and half as much.

If you think it's going to take an hour, it will take two, and if you have a short questionnaire, then as I say, the voir dire gets to be longer. If you have a long questionnaire, you will be able to deal with strikes early. Ms. Van Steenburgh is right. You can do any admonition that you want, and you're going to do that in the opening instructions to the jury. Don't look on the Internet, and she's right. They're going to look on the Internet.

So you're not going to be able to avoid that one way or another. You can put the admonition in the front of the questionnaire, and they will either follow it or they won't. They will either follow your instruction at the beginning of trial or they won't. I'm not so sure that that worries me a whole heck of a lot. I mean, jurors do decide cases on the evidence and the presentations.

Whether they do their own research or they don't do their own research, they're going to listen to the experts. So I don't think any out of court research is going to be particularly problematic for us.

We have, there are scheduling issues with witnesses, as you'll hear, with some of the defense witnesses. We've got our witnesses lined up. Our experts, we have five experts. They have made plane reservations. They have made hotel reservations, and even to throw it off a day because we don't get to the first witness until Wednesday or late Tuesday is really going to throw us off.

THE COURT: I don't think it would do that. At most I think this would probably take an extra, maybe an hour and a half or so. If you assume, say, half an hour to 45 minutes to fill it out after they have been orientated --

Why are they coming at nine? Maybe they can come a little earlier than nine o'clock.

THE CLERK: I can change it. She hasn't mailed them out yet.

THE COURT: We can just get them in a little bit earlier to make sure we have a little extra time for working on it. I do have a concern about research ahead of time. Most of the time, I don't want to say all the time because I'm not sure, but most of the time once they're told that they can't do research here in the courtroom, they typically do not.

In fact, I've never found evidence of that. That isn't to say that it doesn't occur, but I mean, usually you

can figure out if someone has some extra knowledge gained by their own research abilities, and it is so easy with the Internet today. I'm thinking it may be best to have them do it in the morning.

I think we can eliminate your concern about starting Tuesday because I still think that the voir dire process likely would go fairly quickly.

MR. GOLDSER: We're okay if we start the first witness first thing Tuesday morning, but if we go beyond that, then we've got problems from our side.

THE COURT: I would expect we may actually -- well, we will see. I mean, it always does take a little bit longer than you think, but I would certainly think that at the latest, the first witness would come Tuesday morning.

MR. GOLDSER: Okay. We're prepared or we will be prepared to start with our first witness Monday afternoon. We would love to be able to do that, especially with Thanksgiving, and as we have played out our schedule, you know, Thanksgiving figures prominently on the plaintiffs' side, and I know it does on the defense side from what they have told me.

So, you know, getting the questionnaire out and deciding what it is and deciding where the voir dire questions come is something that we need your assistance

with.

THE COURT: The Court will wrap up its review in the next day or so of this and get that back to you, but I'm thinking we should do it in the morning, Monday morning, and have them fill it out then.

MR. GOLDSER: Okay. The second set of issues relate to exhibits, and I have two items on the agenda, and they may be not very clear. One is admission of exhibits, and the second is objections to the exhibits. Let me talk about the objections first.

Both sides have submitted to each other our witness lists together with proposed objections, and many of the objections track closely with the various motions in limine and *Daubert* motions, and so we're sitting with long lists of objections that are made based on motions in limine and *Daubert* motions that each side expects will be granted, which may or may not be true.

So we intend to have a meet and confer about what the real objections are, but we can only do that once the Court issues the orders on those pending motions. So we're a little stuck at this point to get to that issue. I want to talk about admission of exhibits whenever you would like me to start that, unless you have something to say about the objection process.

THE COURT: No. We should be, we are close to

getting orders out here, so if you can meet and confer after that, then we will see what is left to resolve.

MR. GOLDSER: All right. Will we want to schedule another pretrial before we actually start trial to go over things that are left in the way of objections?

THE COURT: Possibly. Let's talk about that when we get done here today. I have a bit of a, as you know, we were originally going to start next week, and then because I have a matter that is going to take me out of town most of the week, it makes it difficult to find a time during next week to schedule, but there may be some time -- I have to look at Thursday's schedule when I get back.

MR. GOLDSER: And this concept of admission of exhibits, let me explain what I mean by that. There is an issue kind of floating around about how do you tell the story of what happened in Europe and how it affected the United States. It goes to the foreign regulatory motion. It goes to the Cheryl Blume *Daubert* motion. It goes to the corporate representative subpoena.

Plaintiffs have a story to tell about what happened in Europe, and much of that story is laid out in the documents, and we have a variety of ways that we can do that. One way is to have Cheryl Blume tell all or part of the story as the historian as it relates to the regulatory context.

You have heard me make that argument in the *Daubert* motion context. In a little bit we will be talking about the corporate representative subpoena and how we use the documents and tell the story through the corporate representative, if that subpoena is upheld. Alternatively another way of doing this is to say, all right, Exhibits 1 through 100 are admitted without any further testimony or foundation.

I mean, they're all business records, and they're all regularly kept, and as the defendant has said throughout, they have all been maintained and produced in the ordinary course of business, which I think qualifies them for the appropriate hearsay objection.

So we could just agree that the exhibits or many of them will be admitted, and then we can use them either in opening or closing to tell the story via argument because the exhibits are in. I just wanted to put that whole question out there.

I'm not sure if there is anything that needs to be decided about it, but as I think about the overall presentation of the evidence and the story, there are a variety of ways of doing it, and we just need direction from the Court about which way it is that we're allowed or multiple ways that we're allowed to present that story, and as I say, there are three possible ways.

We would like to use them all, of course, but if you restrict us in one, I would ask you to give us some slack on another so that at least we can tell the story, and that will be part of my corporate representative argument. So that's the issue around exhibits and admission and how we use them as we go forward in the trial.

THE COURT: Mr. Robinson?

MR. ROBINSON: Good afternoon, Your Honor. Bill Robinson for the defendants. On the question of the admission of exhibits, they have listed over 1400 exhibits. Many of those exhibits are documents that were produced from the files of the defendants, but there are substantial number of documents that were produced from other sources. They either obtained them from Aventis. They obtained them from Ingenix or other third parties that are not involved in the case.

With respect to the objections, we have agreed that documents that came from our files that were prepared by Johnson & Johnson are our business records. There are documents in our files that clearly came from other sources, for example European documents. We did not agree that those are our business records, and quite frankly, Your Honor, there will be authenticity questions and other objections to many of those documents.

In terms of some mass agreement in advance that certain exhibits are admitted into evidence, we can sit down with them, as Mr. Goldser suggests, when we get the Court's rulings on these various motions and meet and confer on trying to eliminate many of the objections. Every case I have been involved in, the story is told by the witnesses on the stand or testifying through video depositions.

And the exhibits come in through the witnesses, and that's the way we think it ought to be done in this case. So it would not be possible for us to agree in advance to some block of exhibits being automatically admitted. I think the way to do this is to work through with the plaintiffs the objections we have filed, and then they can offer those, if they disagree with us, they can offer those through the appropriate witness at the time of trial.

Thank you.

MR. GOLDSER: I'm hearing mixed messages in that, Your Honor. If an exhibit is not objected to, then I presume it's admitted, end of story. It doesn't then have to be offered through a witness because all objections have been waived, foundation, authenticity, hearsay. All the objections have been waived, so its admitted, and it can be used for whatever purpose at that point.

To be sure, exhibits as to which there are objections we'll have to address one way or another, and we can get there once we know what objections remain. It sounds to me like anything that is stipulated to as admissible is admissible, period, and we can use it either through a witness or in argument.

And that's -- I just wanted to alert the Court to that issue and make sure that I'm not missing something on that and that we will be free to use those exhibits, those agreed upon exhibits, in that fashion.

THE COURT: Well, I presume that exhibits that are not objected to, whoever is not objecting has looked at it carefully and believes that they're admissible and they're authentic and there are no issues relative to them. Am I correct about that? That typically is the case, so I think those exhibits we can treat as being admissible without the need to lay further foundation. So that part is taken care of.

Let's make sure once these rulings are out, you meet and confer, and then if we have a lot of exhibits to take care of, we will take care of them when we get another pretrial conference here set before trial or during trial, as the case may be.

MR. GOLDSER: Okay. That would be fine. The next category addresses depositions. There are two issues

here. Again, the objections to depositions, much of what I said about the exhibits applies to the depositions. We need to await your rulings to have a meet and confer on that, and the other issue is about playing the deposition designations.

There are two ways that that can be handled. Plaintiffs' philosophy, and you will hear this several times today, is that we ought to be able to present our case as our case without anybody jumping in the middle of our case and playing part of their case, i.e. the defense. So our proposition is that we get to play our deposition designations as if we were calling that witness live and those are our deposition designations.

When there is a counter designation, the defense gets to play that as a cross-examination as their own testimony as if it were a cross-examination. That's much more realistic. To be sure, it will be necessary to put it into context, and so if that requires some replay of some piece of it in order to put it into context, that can easily enough be done technologically so that there might be a little bit that is replayed to get the other pieces if necessary.

THE COURT: How much are we talking about by virtue of video depositions?

MR. GOLDSER: How much time?

THE COURT: Yeah. How many? What are we looking at? What's the volume, in other words?

MR. GOLDSER: There are a good dozen witnesses on our side, maybe more. Is it more?

MR. DAMES: It's more.

MS. VAN STEENBURGH: It's a lot more.

MR. GOLDSER: I don't know how many of them we're going to actually play. That is different. We've listed a lot.

THE COURT: You've listed a lot.

MR. GOLDSER: I think there will be a dozen, maybe 15, where there are pieces. Some of them longer. Some of them shorter. We're mindful of the time limits that we have, but I want to say that we're in the 10 to 15 hour range of total time for deposition cuts, which is a lot.

So that's what I'm thinking we're going to have, and then, of course -- I don't believe there is much in the way of defense depositions that will actually get played, but I know that we've counter designated on those as well.

THE COURT: Mr. Robinson?

MR. ROBINSON: There is extensive amount of deposition designations that they have given us. I'm not sure how much they actually intend to use at trial. We can meet and confer on that.

My point, Your Honor, is that when we meet and confer, we may still have disagreements about the admissibility of certain evidence. There are only two ways I know to handle that. One is to bring that matter to the Court before the deposition is played, which is what we do where I practice, or we would just have to make an objection at the time of the playing of the deposition.

THE COURT: I prefer to do it beforehand, sometimes you have a pretrial conference. More often it might be at the end of the day before the next day when something is going to be played when we have the jury gone and out.

MR. ROBINSON: That's fine with us, Your Honor. That is evidence going in to the jury, and to the extent we do have objections after the meet and confer, we need a process for doing that.

THE COURT: What's your view on breaking them apart into more traditional direct examination and cross-examination, as Mr. Goldser is suggests?

MR. ROBINSON: I think the rule, Your Honor, on fairness designations, as I understand the courts that have interpreted that rule, requires the fairness designation to either be read or played at the same time as the testimony.

And what we have done in our counter designations and our fairness designations is to place it with the

designated testimony so that they can splice that in, if the Court rules that that's admissible, to splice that in with the testimony that is then being played. So it's a, it flows in order, in thematic order.

MS. VAN STEENBURGH: Can I say something?

THE COURT: Yeah.

MS. VAN STEENBURGH: The reason, I've seen some of these, and some of the designations are cut off in the middle of what the person is testifying about. So the rule of completeness would suggest that you need to have the entire testimony. So it makes more sense to run it consecutively, especially if the designation from the plaintiff is here and then the answer continues down or it is in context with the first question.

So under the rule of completeness, I think that the courts have ruled that it should run in consecutive order, and that makes more sense.

THE COURT: Mr. Goldser?

MR. GOLDSER: If I have a witness live on the witness stand, I would have the ability to ask that witness about that portion of the testimony in the context in which I want to put it, with or without the rest of the surrounding testimony.

And on redirect or on cross-examination, the other party gets to recite the entirety of that testimony

so that when the other side's depo designation comes in, they may have to replay the portion that I played and play it in the entire context, but that's their job, not mine, and I don't want their testimony coming in in my case.

THE COURT: Well, it's, you know, it's awkward either way. I mean, it's awkward to take something out of the deposition and then play it later and get it out of the context, which is more difficult for a juror to understand. I think it's equally choppy to take it from a different part of the deposition and put it in right after the witness testifies to something that the side offering the deposition testimony is wishing to play.

So it, it is kind of choppy both ways. I mean, most of the time both sides -- a witness, you know, witness X is testifying by video deposition. Both sides designate what they want, and it goes from start to finish that way in the order in which it is done. That seems to me the easiest.

Oftentimes portions will be cut out because it's not relevant and not to be designated. I mean, that's what I normally presume to do. I'm willing to do it another way if everyone can agree on it, but it sounds like we're, both sides are proposing a version of that that might make it more choppy. It might make it less understandable for a jury.

MR. ROBINSON: Your Honor, if I might just add?

THE COURT: Sure.

MR. ROBINSON: The deposition process as the Court recognizes is very different from a direct examination on the stand. These depositions jumped around and thematically a lot. They would talk about something in the morning. Come back to the same subject in the afternoon, et cetera.

That's why I think the rule -- I think it's Rule 32. I don't have my rules with me today -- says that it shall be done, the fairness designations shall be done at the same time, and that's the reason we propose what we propose.

THE COURT: Mr. Goldser, anything else?

MR. GOLDSER: Well, at the risk of repeating myself, what then is offered by plaintiff as their testimony is really defense testimony, and the jury ends up thinking that we're offering a statement that we didn't intend to offer, and there is fairness, but that's not fair to us.

THE COURT: Mr. Dames, did you have something to add?

MR. DAMES: I think our position is -- I was tempted.

THE COURT: Mr. Essig?

MR. ESSIG: I was just going to add as someone who has been in the trenches at a lot of these depositions, I would just add as you might expect probably 85 percent of the testimony in, say, the company witness depositions was elicited by examination by the plaintiffs. So our counters are generally in the context of their examination of sections that they didn't designate that we feel needs to be in for the rule of completeness.

So I think it's more of coherent flow for the jurors if they hear the whole examination in that pattern from Mr. Goldser or whoever took the deposition, as opposed to the little bits that we might have elicited at the end of these depositions, if at all. So I think that would counsel to put all the designations from both sides in at the same time.

Thank you.

THE COURT: Well, I think, we can talk about this further, but let's proceed under the assumption that we're just, we're going to play the video deposition from start to finish with the parts that each side has designated, and I'll give the matter some more thought. I hadn't thought about it before the hearing today.

That's the manner in which I'm normally accustomed to doing it. I think it usually runs most fairly that way for both sides. So let's presume on that,

but I will give it some more thought before we gather again.

MR. GOLDSER: Perhaps if there are some areas of particular concern --

THE COURT: Yes. Absolutely.

MR. GOLDSER: -- we might raise it that way. The next item we talked a little bit about, the first day of trial and scheduling the first day of trial, and I think we have addressed that one already.

Item 11 on the agenda, the testimony of Dr. Kahn and Dr. Segreti, this is the defense issue, but just to preface it, those witnesses are not apparently available because they will be out of the country in the week after Thanksgiving.

We've had a request that those witnesses be called during plaintiffs' case in chief, but I will let them address their request first.

THE COURT: Okay. Mr. Dames?

MR. DAMES: Thank you, Your Honor. There are two witness issues that we have in terms of scheduling. One is Dr. Segreti, and the other is Dr. Kahn, and the -- originally there was, we had these individuals scheduled from the commencement of trial when it was originally set, and when we rechecked as to their availability later, it turned out that those were the two with the issues.

Dr. Segreti is available unfortunately only the 23rd, and Dr. Kahn is going out of the country on the 29th. So I approached plaintiffs' counsel and asked if they could be taken out of order. I understand, you know, the -- I understand the hesitation and the dislike of doing that. In fact, it's probably a dislikable thing on the part of both sides to take witnesses out of order, but that is essentially the way I believe, the only way we can proceed and have them come to trial.

The other alternative, and I mentioned that today to both, to both Mr. Saul and Mr. Goldser, was if we had a brief continuance of the trial, which would commence, what I was going to suggest to the Court, was to commence the 29th. We would have sufficient time to be done well before the holidays, but it's essentially the Thanksgiving holiday issue is making things a little bit more difficult for us, so that was my suggestion.

I think I was not greeted with the kind of enthusiasm that I expected, but there was some reference to the fact that they had their witnesses ticketed, but that's the issue for us, and it's not -- it's basically our desire to present these witnesses.

THE COURT: So Dr. Segreti would have to be on the 23rd at some point in time?

MR. DAMES: Correct, Your Honor.

THE COURT: And how long is his testimony estimated to be?

MR. DAMES: Well, I anticipate the direct examination would be only about an hour or so, so I -- unless they would take a very long time with him, his entire testimony would probably be a couple of hours.

THE COURT: Dr. Kahn?

MR. DAMES: Dr. Kahn would be a bit longer. I suspect he could be anywhere from three to, three to four hours. Apparently, he's shorter than I am. Well, I mean figuratively.

THE COURT: Mr. Robinson is quick.

MR. DAMES: That was a better way.

THE COURT: What days is he available?

MR. DAMES: Just before the 29th. Before Thanksgiving, in other words, Your Honor.

THE COURT: I think this can be explained to jurors that we're accommodating witnesses' schedules, and I would be inclined to allow them to go out of order. I have a great preference for making sure that someone who is available to testify can testify in court rather than by video.

I think that's important to do that, so we will work them in on the days that will work for them.

MR. DAMES: Thank you, Your Honor.

THE COURT: And if we need to do something similar for the other side, we can do that as well.

MR. DAMES: Okay. Thank you, Your Honor.

THE COURT: And I will, of course, explain to the jury what is going on and why.

MR. GOLDSER: Well, let me at least make my record. We certainly oppose that.

THE COURT: I understand.

MR. GOLDSER: Again, it is breaking up the plaintiffs' case and our flow and our witness scheduling, all inappropriate. Right before the Thanksgiving holiday, inappropriate. This notice of this trial date has been out there for a long time. Witnesses have to be at the beck and call of the Court and the parties, especially when they're retained expert witnesses.

I don't think that's really particularly fair to allow them to dictate to us and to plaintiffs what the schedule is, but recognizing the Court's inclination.

THE COURT: I mean, I think the only other alternatives are to have their testimony video'd, which creates extra work at the beginning and perhaps is not sufficiently responsive to needs as the trial goes forward or to change the trial date, and I'm not inclined to change the trial date.

MR. GOLDSER: We would certainly oppose a change

in the trial date. Let me be clear about that, and we had planned on showing some of Dr. Kahn and Dr. Segreti's deposition testimony by video anyway. So we were prepared to call them in our case in chief for those purposes.

Now, having said that, what we would propose as an appropriate solution, if the Court is willing, is willing to accommodate the defense schedule is that we get those witnesses here at plaintiffs' desired date, that plaintiff call them as part of their case in chief as adverse witnesses under Rule 611 I think it is, and that we get to call them for cross-examination in plaintiffs' case in chief and that then the defense gets to do their direct examination on redirect after we call them for cross-examination.

In other words, it's our case. We get to go first even with these witnesses if they want an accommodation to call them out of turn.

THE COURT: Were both of them witnesses that you were going to call through video deposition?

MR. GOLDSER: Yes. Designated testimony on the witness list, the whole shot.

THE COURT: Mr. Robinson or Mr. Dames?

MR. DAMES: Dr. Segreti is an expert witness, not a fact witness, Your Honor, and I believe the, well, the procedure I have always had followed in trials is that we

get to present our own expert testimony on our side of the case.

Dr. Kahn is also a witness who would be giving expert testimony for the defendants and will certainly be here and available to testify on cross for plaintiffs, but also plaintiffs have their designations which they can present on their side of the case.

MR. GOLDSER: That may well be, but if we were doing this in the ordinary course in the ordinary sequence, plaintiffs would present Dr. Segreti first or Dr. Kahn first. We would do it before defense would present those witnesses by video, and I don't recall all the details of what each of them said.

But I recall in particular Dr. Segreti, the portions of his testimony that have been designated is, he is on the Speakers Bureau for Levaquin. What's the Speakers Bureau? It's a promotional tool. It's out there for advertising. It's out there for marketing, and one of their experts is a promotional speaker for Levaquin.

Now, when we present that first and then the defense gets up and presents Dr. Segreti as their expert, the flow of that to plaintiffs is hugely important, and to take that in the reverse sequence that Dr. Segreti gets to come on as an expert, well experienced and well credentialed, and the first thing they hear is how great he

is and then we're stuck with cross-examination, well, you're a Speakers Bureau guy, the strength of our testimony gets lost.

And that's not appropriate, and I strongly object to that. So if those witnesses are going to be accommodated, we get to go first with them.

MR. SAUL: If I may?

THE COURT: Mr. Saul? Sure.

MR. SAUL: One moment, Your Honor. So what the defendants are proposing here is we put on our case, and the day before the Thanksgiving break that they are going to call two of their expert witnesses. I just think that that is, that's just not fair, particularly before Thanksgiving break, and everyone is going to go home for four days and be thinking about the case and do whatever they do.

So I think that on this compromise, Mr. Goldser's suggestion is appropriate that we get to call them a little earlier in the case, and then they get to put them on after we call them so --

THE COURT: Anything else?

MR. DAMES: I don't want to fall into the trap of having to speak last all the time, but Dr. Segreti, if I understand Mr. Goldser's approach, it is that he has a right for an impeaching cross-examination before I have a

right to put on a direct examination of our expert witness because I have asked for them to be taken out of order.

I've had this happen to me, not the solution proposed by Mr. Goldser, but I have had the issue of witnesses out of order before in trials, and it is precisely the way the Court explained. It's explained to the jury how this has happened, why it's necessary.

I have never had a, where it's been permitted that they can present in effect their impeaching material before we have a chance to put the witness on in a direct examination.

MR. GOLDSER: I think Mr. Dames missed my point, and that is if we were operating in the ordinary course, we would present that evidence in our case in chief before their witnesses came on the stand, so why not do it that way anyway.

THE COURT: Well, let me give this some additional thought. I'm inclined not to go with Mr. Goldser's suggestion here and just simply allow them to be called out of order. Obviously, there will be an opportunity for cross-examination right after their direct examination, so I mean, I think whether it's before or after, I'm not sure it makes that much difference.

The jury will get the flavor at the same time anyway, but I will give it some more thought because I

hadn't anticipated the issue ahead of time.

MR. GOLDSER: In that same context, Your Honor, one of the things that we had talked about was the opportunity to call Dr. Seeger early for plaintiffs' case in chief. Again, we have deposition testimony in the can for him, but we would certainly prefer to have him live and be able to take him live.

One of the things that we could request is that he be brought in live as part of plaintiffs' case in chief, rather than resorting just to the deposition transcript, deposition testimony that we have. I don't know that we've really talked about that at any great depth, but if they're going to bring in these two other folks, then let's bring in Dr. Seeger, too, and have him live at the same time.

THE COURT: Why don't you confer about that? I understand the point. That's perhaps a good point, and you should talk about it with the other side.

MR. GOLDSER: The last item on the pretrial scheduling deals with the question of punitive damages evidence. Again, we don't know what you're going to do on the punitive damages motion, but it really relates to the bifurcation question that is in the statute and what's the evidence that comes in in the case in chief and what's the evidence that comes in for punitive damages specifically.

And, again, I may be premature in addressing this

because we don't have punitive damages in the case yet, but assuming that we do, we need to know what the dividing line is. From our perspective, all of the liability facts about sales, marketing, you will hear this in some of the motions in limine, come in in the case in chief and not on the punitive damages side.

And really the only thing that I see necessary on the punitive damages evidence will be the corporate financial status in terms of the balance sheet. We believe that the financial information, as you saw in our motions in limine, is related to motive and intent. We believe that the sales and marketing efforts relate to tainting the marketplace and what emanates out to doctors either directly or indirectly.

So all of that stuff we think comes in in the case in chief, not on punitive damages, but there is going to be a dividing line somewhere between what's on the first part of the trial and what's on the second part of the trial, and we would certainly like the Court's direction on where that dividing line is.

MS. VAN STEENBURGH: The only thought that came --

THE COURT: You should have a baton over there. You can just pass the baton.

MS. VAN STEENBURGH: Well, the only thought that

came to my mind is that maybe this is a premature question because there are, there is a motion in limine, and I think maybe one of the *Daubert* motions may address this, but there is a motion in limine about marketing materials and sales materials post prescription, and that may take care of a lot of this information in terms of the question that Mr. Goldser has raised.

THE COURT: Well, the motion to amend, you know, surely will be resolved shortly, and if there is an issue following that, then the Court will take it up, and you can file briefs.

MR. GOLDSER: I believe that covers all of the trial scheduling, trial processing motions, unless defense has anything else you want to raise?

MR. ROBINSON: I'm sorry.

MR. DAMES: No.

MR. GOLDSER: Your Honor, anything that you need to talk about in terms of pretrial scheduling?

THE COURT: I don't think so. I think we have covered -- did you have any issues to talk about today on jury instructions?

MR. GOLDSER: Oh, you're right. I didn't mention that. Thank you. I just wanted to get that on the list so it's out there. I believe you have proposed jury instructions from both sides. My guess is that you won't

rule on instructions until late in the case or at the close of the case, but certainly anything that you can give us in the way of your thoughts on jury instructions is certainly helpful towards presenting evidence.

THE COURT: Well, here's what we will do. Once we have these various pretrial related matters resolved and taken care of, and that has obviously been the central focus up until to this point, then we will turn to jury instructions. I would like to get a draft out to both sides as soon as possible. Again, it will depend on how much more we need to resolve pretrial because that's where the attention is focused right now.

Once that is done, we will turn our focus to jury instructions. My normal practice which I intend to follow in this case is to submit a draft. We will follow up that draft with a meeting, and the initial meeting on the instructions is typically done without me present, just with the law clerk who is working on the case. You can go through it carefully. We can better understand your thinking where there are problems with the draft, where there are things missing.

Typically a second draft then is sent out, and we will follow that up with a conference with the Court. That will probably be mid trial or a little bit later as we see how the evidence is shaping up, and there are some issues

obviously that won't be able to be wrapped up until the end, but that's my intention there.

MR. GOLDSER: Okay. That brings us to the motions that are pending for today. We got your message that there are several that you would like us to focus on. From the defense side, the post 2005 labeling and the foreign regulatory motion. From the plaintiffs' side, the what is called evidence of other products and the other potential causes -- well, I don't think it was called other potential causes of injury, but that's the way I think about it, and the Altman motion.

With the Court's permission, what I think we would like to do is address the motions in limine in general and talk about where they fit into the scheme of things, and then I would like, again if the defense is willing to do it, to let them take their motions first on the post 2005 labeling and the foreign regulatory, and we will follow with our motions.

Does that work?

THE COURT: That's fine.

MR. GOLDSER: I believe Mr. Saul would like to address the motions in general first.

THE COURT: That's fine. Let's go for about 15 minutes or so, and then we will take a short break, and then we will be back to finish.

Go ahead, Mr. Saul.

MR. SAUL: Thank you, Your Honor. I think I can be relatively brief here. It seems to me, particularly in light that we do not have the *Daubert* motions, that these in limine motions are difficult to decide. They're particularly difficult to decide, and they're asking the Court to make evidentiary rulings when in fact the Court, it would be difficult for the Court to make these rulings not knowing the evidence that is going in.

So the law generally on in limine motions is that you have to, if there is an exception to any rule, that you have to, that you can't decide in limine, that you have to decide at the time of trial. So plaintiffs' position essentially is that these pretty much across the board that these should not be decided as in limine motions but rather evidentiary motions under Rule 402.

With that being said, I would just like to have about five minutes to talk about how we view this case going forward.

THE COURT: Sure.

MR. SAUL: What we think the defendants' case is and what we think the plaintiffs' case is because these motions are, I think they relate well to a brief explanation. How plaintiffs see the defendants' case is, it's a reasonably simple case.

Number one, that this is a great drug. Levaquin is a great drug and it saves lives.

THE COURT: This is the plaintiffs' view as to how the defendants --

MR. SAUL: We have been doing this for four and a half years.

THE COURT: I'm just making sure I get the context here.

MR. DAMES: So far, so good.

MR. SAUL: It saved my life and saved others' lives so -- the problem is that they're going to attempt to use evidence about community acquired pneumonia. It's a very, very strong antibiotic, Levaquin, and I think that it's generally accepted and even our witnesses say that it's a good drug for community acquired pneumonia.

However, we're trying the Schedin case, and this drug was used for Mr. Schedin who was suffering from bronchitis. We don't believe that all this evidence of what a wonderful drug this is should go in, only evidence about its relationship and its indications and side effects when used for bronchitis.

So number one, it's a great drug. Number two, the defendants are going to say, whenever we learned of problems, we warned. We went to the FDA, and we warned. Consistent with that, their position is that the FDA told

us what to do, they made us do it.

The plaintiffs' case is quite different, that the defendants when they knew that this change was coming in Europe, they took this study away from Aventis, who was marketing the drug in Europe, and in doing that, they, they submitted a really little label change to the FDA in order to preempt the FDA from doing the black box, which eventually came in.

So the defendants' case is that we warned. I mean the defendants' case is we warned, we kept warning. The plaintiffs' case is, no, you didn't warn. You put in a little, tiny warning so you wouldn't get hammered by the FDA.

The next issue or the theme of their case is that this is a very rare occurrence and that this only happens very rarely, and that is the basis of one of our motions in limine. The Court has already ruled that they cannot put in evidence as to the rarity, and when it becomes my time to argue that, I will be happy to do that.

And the fourth is, the defendants' case is that it was corticosteroids that caused the injury and not Levaquin, and Mr. Goldser will be speaking about that, but in a nut shell, that's the defendants' case, and that's pretty much the plaintiffs' case.

The plaintiffs' case is that they knew that the

FDA would require black box. They took the study away. They did this ginned up Ingenix study. They took control of the situation away from Europe to protect what they said is their label in the United States for marketing purposes. In that period protecting their labeling, they made eight to ten billion dollars.

In a nut shell, I believe that's what the two cases are about, and I think that these motions that we're about to hear surround those concepts. Thank you.

THE COURT: Thank you, Mr. Saul.

Okay. Who is first? Mr. Dames or Mr. Robinson?

MR. ROBINSON: Good afternoon, Your Honor. I'll address briefly the defendants' motion in limine to exclude evidence concerning foreign regulatory actions, proposed label changes in Europe, dear doctor letters in Europe and matters that relate to the drug in Europe.

As the Court knows, Johnson & Johnson did not market this drug in Europe. It was marketed by our marketing partner Aventis who holds the licensing agreement with Daichi for Europe. J & J holds the licensing agreement for the United States, and the first thing I will say, Your Honor, is that we are not asking the Court to exclude the data which originated in Europe, and I'll explain that in a moment.

At least the epidemiological data from Europe we

think would be admissible in the case. What we are asking the Court to exclude are the actions and recommendations taken by the regulatory authorities in Europe as a result of some of this data. As background, Your Honor, this drug was marketed I think first in 1998 in Europe and then received wide marketing beginning in 2000 in Europe.

In 2001, there was a reported increase in reporting rates of tendon disorders associated with levofloxacin. It's called Tavanic in Europe. This came to our attention through the French originally through Aventis, and there was a meeting held in New York by the marketing partners, and you're going to hear evidence about that and what came out of that meeting.

In essence a couple of things came out of that meeting. First of all, there were plans to do epidemiological studies because this data was all based on adverse event reporting, and the second thing that came out of it is, Johnson & Johnson, the testimony will show, looked at their own database to see if they had any increased reporting in our database here in the United States, and they did not see that.

Nevertheless, given the possibility that there might be some increase, especially in people using corticosteroids and the elderly, that was added to the warning voluntarily by a changes being effected, labeling

change, in October of 2001. The epidemiology studies then followed. Aventis started planning for its two studies in Europe.

Johnson & Johnson through Ingenix sponsored a study here in the United States, and you're going to hear testimony about those studies. The Aventis studies in Europe were finished in January of 2002. Johnson & Johnson received copies of those reports, analyzed them, and really determined that they weren't very valid studies.

They were also analyzed by the MCA, the Medicines Control Agency, in the UK by a single person, an assessor named Dr. Suvarna. That assessment report is listed on plaintiffs' exhibit list. Within that assessment report, Dr. Suvarna came to the conclusion that the label in Europe, there was a recommendation for the change in the label in Europe to say, and this is cited at page 5 of our papers, tendon disorders may occur more frequently with levofloxacin than with some other fluoroquinolones. Epidemiologic data suggests a possible doubling of risk relative to ciprofloxacin.

A couple of quick observations about that. There were no Levaquin tendon rupture reports in any of those studies in Europe. This is clearly limited to tendinopathy, and it is a recommendation that was never adopted by the MCA or any foreign regulatory agency. That

assessor's report is attached as Exhibit D to the papers, the motion we filed in this case.

In addition to that specific document, other documents that we think fall within this category are dear doctor letters which were sent out by various European agencies in the fall of 2001 and maybe early 2002, and also proposed label changes in Switzerland by what is called Swiss Medic, which is their regulatory agency.

These type documents, this type testimony, Your Honor, we submit is inadmissible under Rules 402, 403, the hearsay rules and essentially because the foreign regulatory actions really have no effect on what happens in the United States. As this Court knows, regulatory authority for drugs marketed in this country is held by the FDA.

And the courts, including the *Baycol* case, the *Seroquel* case and the other cases we have cited in our brief are fairly uniform in excluding evidence, not only evidence of final regulatory changes or label changes in foreign countries, but also certainly any proposed, nonadopted regulatory label changes, such as what we have here.

Now, in our brief, we have laid forth our arguments that these documents are hearsay. There is some question about whether the plaintiffs have properly

authenticated the assessor's report. We have nothing on that yet. They clearly do not fall within Rule 803(8)(c) or Rule 803(6), the business records exception, for the reasons we've stated in our brief.

THE COURT: The plaintiffs argue that they're not hearsay because they are really only being offered for notice purposes and not for the truth of the matter being asserted.

MR. ROBINSON: I would like to address the notice issue, Your Honor. We don't think it goes to the notice issue, and that was, I believe, one of the -- the issue in the *Baycol* case and the *Seroquel* case. The courts specifically said in those cases that the prejudicial value and confusion to the jury far outweighs the question of notice.

Further, what is the notice that is issued -- at issue here? Is it the notice that there was a proposed label change in Europe, or is it the notice that there was data originating from Europe in one study which showed that levofloxacin had a higher risk ratio than ciprofloxacin for tendinopathies.

The company had that data. They analyzed that data. There are documents we are going to put into evidence showing why the company did not accept that data for the reasons that are set forth in those documents. So

to argue that we should have notice that there was this study result in Europe that showed X, we had that information.

It's not a question of notice, and the question of whether we knew or not that there was a proposed label change, which was not adopted in Europe, we think it's totally irrelevant to the issues in this case.

THE COURT: But ultimately was any regulatory action taken in Europe different than what was done by the FDA?

MR. ROBINSON: There was no regulatory action of that nature taken in Europe, and in fact, what happened in Europe, if I recall correctly, there was a minor label change which added essentially the same language in Europe that had already been added here in the United States, and that language specifically was that the risk of tendon disorders is increased in people taking corticosteroids and especially the elderly.

The FDA here in the United States approved that changes being effected change here, and the FDA has never ordered any kind of comparative language such as this, and in fact, there will be testimony in this case that you can't do that in this country unless there is either a prospective randomized clinical trial, and this is under FDA rules, or a waiver.

And furthermore, Your Honor, in Europe, in October of 2003 after all the data was accumulated, and this is in page 4 of our papers. After all the data was accumulated, the adverse event data, the Van der Linden studies, the Aventis studies and even the Ingenix study, the MHRA, as the MCA was known at that time, went through a detailed analysis of that data and concluded that no label change would be required in Europe.

So there never was a label change, and to my knowledge to this day there has not been that label change of a comparative risk of two drugs in the European situation. Thank you.

THE COURT: Thank you, Mr. Robinson.

Mr. Goldser?

MR. GOLDSER: Let's see if I can make this work today. We're in luck.

Your Honor, a motion in limine has to have a couple of prerequisites to it. Number one, it's got to be specific as to the evidence that is being sought to be excluded; and number two, that evidence can have no admissible purpose whatsoever. It might be inadmissible for one reason but admissible for another, it comes in, and a motion in limine has to eliminate all of the reasons.

As to the first item, I finally understand Mr. Robinson to be objecting to I believe four documents.

One is the MCA assessor's report which is dated April of '02. The second and third --

THE COURT: From the UK?

MR. GOLDSER: From the UK. The second and third are two dear doctor letters, one that was sent out in France and the other that was sent out in Italy. My understanding is that those were sent out by the company, not the agencies; and number three, the Swiss Medic recommendation as to the label change. That's it. If there are other documents, they're not specific enough in their motion to be talking about those here today. I'm going to talk about those four documents and those four documents alone.

The MCA document is as Mr. Robinson describes. It is an assessor's recommendation about a label change, and as the Court correctly said, it's not about whether or not there ought to be a label change. That's not why it's being offered. It's being offered to show the threat to Aventis and Johnson & Johnson of their label in Europe and in the United States.

You saw when we were here on the Blume motion, I played you the clip from Dr. Kahn. I said these words dozens of times now. What goes on in Europe will be around the world in a nanosecond. They were dreadfully afraid that what was going to go on with that recommendation would

affect the label in the United States, the market in the United States, and then it would happen so fast, this was April of '02, that it would affect the fall flu season in 2002.

And you saw some of the financial information that we presented before and will present at trial. This was a billion dollar a year drug. Its patent is going to expire next year, and the most important thing for a pharmaceutical company is to put off any threats to its patent.

How many patent cases do you see in here? I don't know how many patent cases you see about drugs, but the ANDA anti trust and patent cases are all over the place with generics trying to impinge upon the pharmaceutical company's patents. So protecting that label and protecting that patent protects billions of dollars, and it's about those billions of dollars that we're talking.

So when you get to the documents, and I showed you some of these in the punitive damages motion, but they're relevant here again. We could do with an urgent meeting between those of us present at the Aventis/Daichi meeting. This is July 26th, 2001. That's the wrong one. Here it is.

This is Jim Kahn writing. The repercussions from an adverse regulatory decision in France, who can forget

sparfloxacin -- this is consistent with his video clip -- would be immediate and devastating. So let's act promptly. So what is going on in the regulatory arena in France is going to have a potentially devastating impact on the market.

This is Jim Kahn's memo. You have seen this before. The first paragraph: There is a very worrisome regulatory situation that is in Europe. It has clear and serious implications for our marketing of Levaquin and could have an impact in the U. S. as early as the coming respiratory season. That's actually the 2001 respiratory season. It is urgent and requires our immediate attention.

The memo goes on. You remember I read you other parts of it. What is happening in Europe is going to have an impact on the American label. It's going to have an impact on the American market, and so this recommendation is not about a foreign regulatory legal stance that should be implicated in the United States.

The cases when you go back and look at them say that because the law is different in Europe and there are different legal standards, it's not a res judicata type impact in the United States. We're not going anywhere close to that. We're talking about what was going on there and how it impacted the United States' market.

The entire franchise was riding on a single toss.

I think that was Jim Kahn's statement again, again the regulatory context. Stakes have gone up. I think this was Larry Johnson if I remember it correctly. Larry Johnson, as you see from the e-mails, the stakes have gone up. This is Germany's regulatory agency talking now.

Now, these documents I don't hear Mr. Robinson suggesting are covered by his motion in limine, so if these documents are admissible, how do you keep out the MCA evaluation? How do you keep out the Swiss Medic evaluation? These documents are talking about that, those regulatory actions. Not because they're legal standards but because they're the things that the company is reacting to.

A contraindication is similar to a withdrawal. This one is a good one if I can find it. This is the U. S. or the MCA guy, Dr. Steven Evans. He stresses they were able to convince other EU countries for not making a contraindication with the prerequisite that we would provide some epi data soon. He felt that if a contraindication were added, it essentially was the same as a withdrawal of the product because of the contraindication of its use with steroids.

This is the MCA doctor talking. He's saying that if you guys don't help me with epidemiology, we're going to issue a contraindication and that is going to affect you

just like a withdrawal. This is happening in Europe. This is Johnson & Johnson taking over from Aventis the study and ultimately generating the Ingenix study.

Let me fast forward a little bit. This stuff was happening in the summer and fall of 2001. The study, the Aventis Company did their own studies in January of 2002. For Johnson & Johnson, they were horrendous results. That's what generated the MCA recommendation in April of 2002.

And I'm not quite sure how the European agencies worked, but they all worked together, so France and Europe and Belgium and Germany and Switzerland, they all had some combined relationship that I don't quite understand, but ultimately, there was a meeting in Belgium in May. When the MCA's recommendation was out, the Ingenix epidemiology study was not done. It was in process, and Belgium was about ready to go forward with the same recommendation.

And if you look at the sequence of e-mails in the first two weeks of May between Aventis and Johnson & Johnson to a great extent, they may have been originated in Aventis, but they were received by Johnson & Johnson so that makes them a regularly kept business record, and they are produced with LEVP Bate's numbers on them.

You can see the panic that existed in the company about what was about to happen and the utter relief that

occurred after the meeting. I think it was May 13. The e-mail came out maybe May 22nd. Well, we survived that one. Mr. Robinson is right. There never was a recommendation for a label change in Europe because of the Ingenix study, because the Ingenix study was created by Johnson & Johnson, because Johnson & Johnson took it away from Aventis, because Johnson & Johnson was able to convince the European authorities to focus on tendon ruptures not tendinopathies.

They were able to change the focus of the study, and in fact, there was a point in time, I don't remember the date, when Johnson & Johnson was so concerned that Dr. Kahn appeared before the MCA personally. Despite Mr. Robinson's protestations throughout this case that Johnson & Johnson never had anything to do with the MCA, Kahn appeared twice personally in front of the MCA, right? Once?

MR. SAUL: I don't know that it was Kahn. Two of Johnson & Johnson employees appeared.

MR. GOLDSER: All right. I'm pretty sure it was Kahn at least once. I thought it was Kahn twice. Clearly, Johnson & Johnson appeared themselves in front of the MCA, despite defense protestation to the contrary. So the fact that it was happening over there and J & J had nothing to do with it is wrong, and this is not summary judgment.

This is evidence. This is relevance. This is whether it fits into an exception of the hearsay rule or in fact is not hearsay at all, which we believe. We think all of this foreign regulatory material is relevant, particularly the four documents that Mr. Robinson is focused on and only those four documents because that's the extent of his motion, and I could show you more, but I don't think I need to.

THE COURT: That's fine.

Mr. Robinson, anything else?

MR. ROBINSON: Your Honor, I think you can see this is going to be an interesting case. As to Dr. Kahn, Dr. Kahn appeared before the MCA on a matter of hepatotoxicity. My understanding is it had absolutely nothing to do with tendon disorders. Okay?

The slides and documents that Mr. Goldser has just showed you are all dated in 2001. There was no actual proposed regulatory action in 2001. It was supposed by Johnson & Johnson and Aventis that there might be regulatory action based on that adverse event reporting data.

These documents that he has showed you don't go to our motion. They may or may not be admissible for other reasons. The documents that generated the recommendation for a change in the European label came out of the German

IMS study, which was reported in January of 2002, and the assessor's report reviewing that study of April 2002.

A final point, Your Honor: We are not limiting our motion to those four groups of documents, if you will. Our motion clearly asked for exclusion of correspondence and other communications related to the proposed regulatory changes in Europe, and that would be the MCA assessor's report, the proposed changes on that and the Swiss Medic and the dear doctor letters, but there are a lot of documents in this case.

Aventis produced a tremendous number of documents. We produced a tremendous number of documents, so the motion goes to any documents in addition to those specific ones I identified for the Court, and I think we made that clear in the introduction to our motion. Thank you.

MR. GOLDSER: I'm happy to show you the May of 2002 documents to respond to Mr. Robinson's argument, if you would like. I would be happy to do that. Otherwise, I think you get the gist of what we're talking about. There are such documents.

THE COURT: I think that's fine. I'm going to give this matter a little bit more thought. I would like to do a little bit more research. I'm inclined to deny the motion, but to watch this matter closely at the trial and

make sure that we're not getting too far into a subject that might be confusing for the jury, and I do have some concern about that, but I'm going to reserve ruling on it until I've done a little bit additional research into the case law on this subject.

And why don't we before we get to the next motion, Mr. Goldser, let's take maybe a three or four minute break just to move around. Okay?

THE CLERK: All rise.

(Recess taken.)

(In open court.)

THE COURT: You may be seated. Okay.

Mr. Dames.

MR. DAMES: Okay, Your Honor. I'm not going to be long, and this is the motion concerning the post event label changes in effect. The black box warning is essentially the issue apparently. Our position is relatively straightforward, Your Honor. The later warnings are, have no probative value. They are not relevant to the issues that concern the warning that was in use and seen and received by Dr. Beecher in 2004. The black box warning obviously was promulgated in July of 2008, a good number of

years later.

Now, the later warnings can't be admitted under some exception that they can be used to establish causation, which would be one method to get later warnings in, because those warnings, warnings don't have to be based on an assessment of causation. There is a lesson standard for inclusion in the warnings.

Now as to the later warnings, there seems to be, and the brief points it out, an agreement among both plaintiffs' experts and our own that Ms. Blume herself acknowledges the Levaquin information from 2006 and 2007 wasn't relevant because it occurs long after the important dates in this litigation, and that's seen, as we point out, in our brief in the response to the Blume *Daubert* motion that plaintiffs filed.

There also is a statement and an admission there that plaintiffs' expert will not testify that we should have implemented a boxed warning earlier. Plaintiffs' expert will also testify, should you admit the testimony over our *Daubert* challenge, that defendants could not have placed a boxed warning earlier because in fact the FDA as to a boxed warning must be the initiator. It initiates boxed warnings, not a manufacturer. It in effect imposes boxed warnings.

Now, the FDA itself when it announced the boxed

warning, when it implemented it, announced that it was based on new evidence. The FDA had a new assessment upon which its conclusion that a box warning was necessary was based. So on the peculiar facts, not so peculiar but under the facts of this case, four years later a box warning is imposed by the FDA.

It would be -- it's clear from the evidence of the experts that it is the FDA's prerogative to impose a box warning and not the manufacturer's. Their own experts says that J & J could not have put on a box warning before. Clearly, the prejudicial impact of admitting into evidence a boxed warning statement or reference to the boxed warnings at trial in this case far outweighs the minimal, in fact I would suggest none, probative value of such evidence.

I know the Court had asked some reference, I mean, raised the question about the *Wyeth* case. I think in this instance, based on the testimony by deposition and by plaintiffs' expert, plaintiffs's own report, the admissions in the response to the *Daubert* motion, it is clear that when it comes to a boxed warning issue and the box warning issue as to Levaquin, the FDA has spoken.

It's issued regulations. It has spoken very clearly and after review and comment period that it is the body that imposes boxed warnings. Manufacturers cannot do

so, and in this instance, frankly factually there is no dispute about that.

THE COURT: Have there been cases yet addressing the issue of whether *Wyeth*, the theory of *Wyeth*, the central holding would apply to a black box case?

MR. DAMES: I'm not aware of any reported decisions on that, Your Honor. We would certainly have put it in a brief if we had found some, but I think that probably will be one of the next challenges, hopefully not in this case, of course --

THE COURT: Depends on who is making the challenge.

MR. DAMES: But it is clearly an avenue open under the *Wyeth* holding, I believe. Thank you, Your Honor.

THE COURT: Mr. Goldser?

MR. GOLDSER: Thank you, Your Honor. Again, let me set up here quickly. I always have something to show you. The screen disappeared on there. I'm going to have to function -- all right. I'll function from memory.

In any event, as I said before the last motion, Your Honor, we have to be very specific about which evidence the motion addresses, and I have heard Mr. Dames address one item in particular, and that is the black box warning itself.

THE COURT: Is this your screen right here?

MR. GOLDSER: Uh-huh, it is. There we go. Wonderful. Thank you.

The black box warning itself is all we're talking about. Let me talk about black box warnings as a small concept in this case because it's going to come up in a variety of ways. In the, in 2005, the Illinois Attorney General filed a citizens petition based on their analysis with their health department seeking a black box warning for Levaquin.

In 2006, Public Citizen did the same thing, seeking a black box warning for Levaquin. The subject of black box warnings and what they are are going to come up. The other way black box warnings are going to come up is --

THE COURT: Just one second. Okay. Sorry.

MR. GOLDSER: That's okay. The other way the subject of black box warnings is going to come up is in a marketing context. One of the documents that should be admissible because a witness testified to it is a 2003 launch quick tips guide to sales representatives, and in that guide, it says, you should be telling doctors about the fact that Tequin and Avelox, other fluoroquinolones, have black box warnings on them with regard to a heart problem, prolonged QT syndrome, and that Levaquin does not have a black box warning on it.

What's a black box warning? We're going to have

to explain what a black box warning is and when it comes up and how it's used. That's a marketing thing, and when you get out to comparing drugs, because they say they're not allowed to compare drugs, in fact, they have compared drugs. So you're going to have that problem. It's going to come up.

Another way it's going to come up is what is on the screen right now. This is a 2008 letter the FDA sent to Johnson & Johnson, to Ortho-McNeil, telling them that they had to impose a black box warning, and this is what Mr. Dames referred to when he said there is a new analysis.

And that bottom paragraph, and it's long enough that I probably shouldn't take the trouble to read the whole thing, but if you can listen to me and read at the same time, what that paragraph says is that we, the FDA, have undertaken a new analysis of the data, and we find that the warning that is in effect right now is inadequate, and you need to change it.

Now, does their motion encompass this letter? I don't think so because this is not the black box warning itself. This is the letter announcing the black box warning, and this is about a data analysis, not the black box warning. What is the data analysis? The data analysis is analysis of data that was mostly around prior to Mr. Schedin's prescription in 2005.

The only thing that came out since that prescription in the way of data, there would be new adverse event reports that the FDA has received, and as you saw the charts from Dr. Blume and Mr. Altman that came in as part of that motion, there wasn't a huge change from 2005 to 2008 when this letter was out that would show any great difference.

There was a study called the Ingenix study that came out in 2006. Of course, the FDA had that prior to 2005 in an early draft, and there were one or two other articles that were published, not of great consequence, nothing to really rock the world. So this new data analysis is really only a rubric to fit into the new regulation that was promulgated in 2007 whereby the FDA got new powers to finally mandate new warnings which they didn't have prior to the FDA AA that was promulgated, passed by Congress in 2007.

So what should come in is this letter that says, the early warning is inadequate. I agree that the FDA has the authority, the exclusive authority, to issue a black box warning itself, but beyond that, there are lots of things the company could have done by CBE and on its own without FDA prior approval.

For example, in the *Baxter* case, and I think we have provided this to you before. In the event, we

haven't -- a black box warning was under discussion with the FDA, and Pfizer, I think it was, issued dear doctor letter to all the doctors saying there is going to be a black box warning. You should be paying attention to this, and that was done before the black box warning.

Johnson & Johnson could have done that here. They could have announced the black box warning even though the FDA has the exclusive authority to promulgate the black box warning. In addition, one of the most important things in this case that goes to whether the defense, whether Johnson & Johnson adequately notified physicians of label changes, in 2001 we have the label change that included the corticosteroids.

They published it in the PDR. They didn't do anything else, nothing. Published in plain view is the phrase that you will hear. What they should have done is, they should have had their sales representatives proactively telling doctors about this label change. See, label change, new label, it's in the warning. You should do that proactively.

In Teresa Turano's deposition I asked whether there a policy about doing that. No, there was no such policy. Was there in 2001? I don't know. How about when there was a black box warning? When the black box warning came out with Johnson & Johnson, was there proactive

efforts to call that to the attention of the doctors? Yes, there was.

So it's not about the black box warning itself, but it's about how it was promoted and how it was communicated and the standard of care that Johnson & Johnson itself uses to promulgate information about warnings.

As was taken in the Kathy Riley Govan deposition by Mr. Binstock the other day, they spent millions of dollars promoting new indications when they get a new indication for the drug or a new drug, and they spent virtually nothing on promoting warnings when they came out, not the least of which was a passive/aggressive nonpromotion of the 2001 label change when their standard of care with the black box warning was to be proactive about it.

So there are lots of ways the issue of a black box warning comes into this trial, and the existence of the black box warning itself is going to be made known to this jury. So whether the FDA has the power exclusively to promulgate it or not doesn't matter a hill of beans. We think it comes in.

MR. DAMES: There are parts of which I think I did not see any contradiction of what we said, and so the portion concerning the admissibility of the actual black

box warning in 2008 I think I interpret Mr. Goldser's comments to be that that is a well taken motion and limitation.

He is suggesting, however, that the FDA letter which seeks to form the legal underpinnings of requiring a black box warning somehow is admissible regardless. That FDA warning is an assessment, as it says by its own terms, that based upon this new analysis and also new evidence because it's based upon an analysis of adverse event reports which had been rolling in through the time of the analysis made by the FDA, the FDA's analysis was, we do not find in effect that adverse event reports were declining. Therefore, we believe some additional measures were necessary.

That finding by the FDA is based upon the experience that was occurring right then, and just parenthetically, because sometimes one's mild irritation at the uses of evidence comes out, but 2008 was also the year of the commencement of the litigation, and it was in fact even a little before. And we all understand I think in this courtroom what influences the reporting of adverse events, and litigation is substantially one of them.

But the FDA had made that move. They decided based on that accumulation of evidence through the time of their assessment that they were going to require a black

box. Interestingly enough, the year prior to that, in 2007 J & J was one of the companies that initiated a different format, a format required by the FDA, and J & J was one of the first ones to comply with that, which is highlights of prescribing information.

They made a new label with this new highlights of information that was designed by the FDA, and it sent it around to the physicians, as it did with all their other prescribing information. Every time a doctor is given a sample of the drug, every time a doctor is detailed about a drug, he or she is given the prescribing information that is then current on the drug.

So it's not just being put in the PDR, but in any event, in 2007 this new format, prescribing information, was approved and found to be actually, it was approved by the FDA as a fair label, as a correct label, as an adequate label. It approved it.

So a short time later in 2008, the FDA turns around based upon this different assessment, based upon the accumulation of evidence, and decides they will then add the boxed warning. This doesn't mean that any warning -- we all know this as attorneys, I believe. It by no means means anything about the adequacy or inadequacy of an earlier label, but that, of course, is what is going to be attempted in this case.

There will be references to duties that are not substantiated to highlight warning information to doctors, to have detail people go around and specifically tell doctors of every change in the label even though it is made available to doctors. We're going to be arguing something so separate from the prescription to Mr. Schedin in this case if evidence like this is permitted.

And I, part of me, I have this compulsion to point out that it's interesting that the prescription for Mr. Schedin, the most important and pivotal fact in this case, no one has criticized. No one is suggesting that Mr. Schedin should not have received Levaquin when he did.

It was the appropriate drug to give him. It was based upon published guidelines at this time and current to this day for the condition that he presented, and it cured him of his condition. His own physician had the appropriate label in his possession by his own terms.

So this is not a case of misinformation of somehow overpromotion by the sales representatives, nor is there any indication by anyone that the label that was in use at the time was inadequate, and that is what they are trying to do with this 2008 reference and the black box warning.

Thank you, Your Honor.

MR. GOLDSER: Couple of things, Your Honor?

THE COURT: Sure.

MR. GOLDSER: Again I want to make sure we're distinguishing between summary judgment and introduction of evidence. This is about introduction of evidence and does it have a relevant purpose. This is in part a negligence case. Negligence is about standard of care, what's the duty and was it breached. One of the standards of care is defined by what the company itself does under certain circumstances.

One of the circumstances was, what did they do when the black box came out and how did they tell their sales force to act? They told their sales force to act proactively to tell doctors, whereas they had not previously done that. Is this the standard of care? Well, we would like to offer evidence that it is, and it's about evidence at that point.

The other thing I didn't address and I think is part of this motion is that defense seeks to exclude this evidence on Rule 407, subsequent remedial measures grounds. I just want to make clear that a subsequent remedial measure is an action voluntarily undertaken by the defendant to correct what is perceived as some fault on its part.

This was not voluntary because it was FDA mandated, and it was not undertaken by the defendant. It

was undertaken by the FDA, so Rule 407 does not apply. Finally, the *HRT* litigation, Judge Wilson dealt with about 75 or 100 motions in limine prior to a trial in 2006 and issued kind of a one line or two line order on all of them. This is at 2006 Westlaw 3806391, 2006 Westlaw 3806391, and on this motion, Judge Wilson said:

Wyeth's motion in limine number four to bar reference to post June 1999 labeling changes and dear doctor letter for the HRT drugs is denied, but the parties should attempt to agree on a limiting instruction. Additionally as defendants suggested, all post June 1999 labels seem to be fair game. So in another case, all those labels were allowed into evidence.

So, again, please make your focus on evidence and not summary judgment, as Mr. Dames would like you to do.

THE COURT: Okay. Very well. The Court will take that particular motion under advisement. We'll do some additional work on that and get that out quickly. Okay. We've got several plaintiffs' motions to make here.

MR. GOLDSER: Your Honor, we would also like to --

THE COURT: I'm sorry.

MS. VAN STEENBURGH: Before you go, as long as -- might I? One of the issues on the papers, you don't have the exhibits. This is the one having to do, and actually

perfectly dovetails, the Illinois Attorney General petition and the Public Citizen petition.

Apparently the plaintiffs are going to withdraw from their exhibit list the 1996 petition and substitute the 2006 citizen's petition. So they want the 2005 Public Citizen position and 2006 Attorney General petition. Right, or am I backwards on the dates? The other way. Okay.

I have the 2006 petition that I would like to provide to you, and also because I knew we weren't going to have much time today, we prepared a quick pocket brief that we'll give copies to both sides and to the Court, a couple copies to the Court.

THE COURT: So the Public Citizen petition is in 2006 now, is that right?

MR. GOLDSER: Yes.

THE COURT: Not the '96?

MS. VAN STEENBURGH: Right. And it provides the evidentiary basis under 803(6) and (8) as to why those exceptions don't apply.

THE COURT: Okay.

MS. VAN STEENBURGH: Okay?

THE COURT: Thank you. Go ahead.

MR. GOLDSER: We may need a day or two to respond to this, Your Honor.

THE COURT: That's fine.

MR. GOLDSER: You had asked us to address motions number 1 and number 4 and the Altman motion. Might I suggest on the Altman motion that we hold that in abeyance until the *Daubert* rulings on Cheryl Blume because that will help us further define and refine the Altman motion?

THE COURT: Okay.

MR. GOLDSER: We would also like a few minutes to address our motion number 5 which has to do with tendon disorder as a rare occurrence, and Mr. Saul will address that.

THE COURT: Okay. Go ahead.

MR. SAUL: Thank you, Your Honor. Your Honor may recall that at the selection of bellwether plaintiffs, we moved for consolidation of several plaintiffs. The defendants opposed that, and in speaking with the Court, I suggested that the reason they opposed this is because they did not want the jury to know that this was a common occurrence and not a rare occurrence.

And the Court ruled at that hearing on May 28th as to Mr. Saul's concern about juries seeing that there are more victims, certainly I will not permit the defense, nor I would expect them, to try to argue that this is an isolated kind of situation, that that simply, given the nature of these cases, would not be an appropriate

argument.

That was your ruling. I was unable to attach the portion of the relevant transcript, which we just received in the last day or two. If I might pass a copy?

THE COURT: That's fine.

MR. SAUL: At the hearing on October 14th, 2010, Mr. Dames stated as follows:

Correct. Correct. In fact, there will be a recurring theme in this litigation will be the rarity of exposure of any one of the physicians who appears to the occurrence of tendon rupture from the use of fluoroquinolones.

That's on page 23 of the transcript. In fact, in the last week, Mr. Robinson at a deposition -- are you with me?

THE COURT: Yeah.

MR. SAUL: Last week at a deposition, Mr. Robinson spent a substantial amount of his time in cross-examining Dr. Dai as to the rarity of events. For instance, it's like one in 10,000 people's month years. I don't quite understand what it all means, but the fact is that they're going to try to convince the jury, and this is part of their theme, that this is a rare event.

Your Honor already ruled that they could not, and it was part of the reason for denial of the consolidation

motion, and we would ask -- and we actually conducted our discovery in such a fashion relying upon that. We would ask that they be precluded from attempting to enter this sort of evidence.

Thank you.

THE COURT: Mr. Robinson?

MR. ROBINSON: Your Honor, there is a lot of data on the occurrence rate of this particular illness. The data in the United States showed that the tendon ruptures were one per four million prescriptions. We think that was part of the analysis that was done in 2001. Every study that looked at data came up with some kind of projected incident rate.

The letter that you were just shown by Mr. Goldser from the FDA, in the text of that letter talks about the very rare condition of tendonitis, tendon rupture. These are, these are comments, Your Honor, that we haven't made up. It's not our interpretation of the data.

These are comments by people who have done the studies and have commented based on their own analysis of their data that this is in fact a very rare occurrence. We think that data is admissible.

THE COURT: Do you have the transcript from the May 28th hearing?

MR. GOLDSER: Electronically.

THE COURT: I could just pull it up electronically, too. We'll take a look at this and then resolve this matter.

MR. SAUL: Your Honor, in all fairness, if they're allowed to put this sort of evidence in, we would like to put in evidence that there are now over 3,000 cases dealing with tendon disorders filed in the court.

MR. DAMES: Your Honor, the data, the incidence rate of tendinopathies and tendon rupture and the occurrence of tendon rupture in individuals using fluoroquinolones, to the extent that that's been published and is data that is available, it is what it is. It's the science that is available on it.

I think the comments of the Court earlier concerning an isolated case, it's not isolated. We have warned about tendon rupture, so we clearly aren't suggesting it's so rare we were not on notice and it should not have been put in the warning.

I think the context of the earlier conversation was not for the Court to impose an order restricting us from talking about what the science shows. All of the discovery in this case, and particularly that done by the epidemiologists and in fact plaintiffs' Dr. Zizic, for example, we questioned them and they questioned our

witnesses a lot concerning the frequency and the rate of tendon rupture.

And if there is one, again, I keep saying agreement, but I tried to isolate the agreements that both parties have in this litigation, is that it is a rare occurrence. Dr. Zizic isn't going to contradict the rarity of this occurrence when he hits the witness stand. It's what it is. The data is what it is.

Now, is it something that was foreseeable to us? Obviously, it was in our label. The reason why it's incredibly important to both sides, I would say particularly to us, is the adequacy of the label. The benefits versus risk assessment of the drug is based on the analysis of what is the frequency of this occurrence. That's at least part of the assessment, but we're not arguing contradictions to the science.

We're suggesting that it is the science that is going to tell us from the experts on the witness stand what is the rate of the occurrence.

THE COURT: Okay. We'll take a look at what the Court said earlier.

Go ahead, Mr. Goldser.

MR. GOLDSER: The next motion, plaintiffs' motion, is evidence concerning other products, and we had proposed to talk about a variety of drug, what we call drug

problems that Johnson & Johnson has had over the past year, and there are several reasons why we want to do that.

One, to follow up on the last motion about what, whether an occurrence is rare, we talk about, all right, so what is the standard of care, what is the duty, what is the responsibility of a drug company when they learn about a serious but rare event?

And you'll remember that when we were talking about the confidentiality motion and to try and lift the confidentiality, I gave you a copy of Mr. Weldon's testimony in front of Congress, and one of the motions you have in front of you is a motion to quash that subpoena. One of the reasons we want Mr. Weldon to come in is to testify about what he said in front of Congress.

And one of the things that he said in front of Congress is with regard to quality in general: After we found a substantial quality issue at McNeil, we instituted a broad and precautionary recall of all liquid children's products manufactured in Fort Washington, which we did in the interest of protecting consumers. Although our medical experts and the FDA agreed that the health risk was remote, AKA rare, we believe the right course of action was to proceed with a broad precautionary recall and commence a complete reexamination of McNeil's manufacturing processes.

He said the same thing later on in that statement

with regard to Motrin products: The assessment performed demonstrated that on a statistical basis, a low amount of product, approximately 1 percent of the batches, AKA rare, is potentially still at the retail level. The product from the subject lots found in the stores was removed during the visits.

What did they do in other circumstances when they found a serious but rare health event? If in fact the question of rarity of tendon ruptures comes in, that's not the end of the story. That only opens the door to talking about, so what do you do under those circumstances, and what did they do in other instances when they, Johnson & Johnson, found a rare event, and what did their chairman say in front of Congress about what they do about such rare events?

Well, Mr. Weldon has said that. He said that they take precautionary risks. They have issued recalls in rare events under other circumstances, and that's the standard of care, and they breached it here. Mr. Weldon should be able to talk about that. He should come in, and he should be able to talk about what the company has done under other circumstances because he is an embodiment of the standard of care.

And as Judge Wilson said in that *HRT* order on a very similar motion, which I will get to in a second, the

issues that Wyeth described in points four and five seem to open the door to plaintiffs' evidence, which would put such conduct into context. So if you get the goose, you get the gander. You've got to have the whole story about the rarity of tendon occurrences and what it means.

So talking about other products, that's one context for it, but there is another context, and frankly, it's an issue that comes in through the back door of this motion. Throughout the course of this case from time to time, my learned adversaries have talked about what a good company Johnson & Johnson is.

And I fully expect them to talk about Johnson & Johnson as the baby powder company and the diaper company and the company that brings you all these good products and what good company Johnson & Johnson is and in the Levaquin context in particular how we make drugs that save lives.

If they can talk about what a good company Johnson & Johnson is, we get to tell the other side of that story. So as Judge Wilson said in that same order, it's number two, plaintiffs' motion in limine number two, Wyeth will be permitted to put on very brief evidence as to how long it has been in business, how many employees it has and generally what it does for a living. And that's a motion to grant in part and deny in part a motion to bar references to good acts of Wyeth as a company.

So if they want to talk about how good a company is, Johnson & Johnson is, and how great a product Levaquin is, then we get to present the other side of the coin, and talking about other recalls and other products is the other side of that coin.

THE COURT: Did the Eighth Circuit impose a substantially similar standard here for determination of whether you can bring in other products that may have been subject to recall or otherwise evidence a less than good company, whatever that might be?

MR. GOLDSER: Sure. Not in this context. The cases that defendants have cited about being able to talk about other products have only to do with product A and product B, and if the case in litigation is over product A and there was a recall of product B, the proof was designed to prove that there is a defect in B, therefore there was a defect in A.

And the purpose was to prove liability as to A because there was a recall as to B. That's not what we're talking about here. We're talking about standard of care in terms of what this company does when they recognize there is a remote risk of a product and warnings and issues of that kind.

THE COURT: Isn't that somewhat closely related, though? I mean, you're not, I think you're not technically

seeking to admit other evidence of other product recalls as evidence of a defect in this product, but it seems at least somewhat close to that when you're making that argument.

MR. GOLDSER: There is a real difference in a defect in design of a product and what the standard of care a company uses to deal with warnings of products, warnings about pharmaceutical products, and what they do when there is a remote issue. And there are standards about how precautionary their activities are and can be as a matter of corporate policy, as a corporate philosophy, as a corporate ethic.

Now, the company has a --

THE COURT: The doctrine doesn't apply, in your view, in warnings cases?

MR. GOLDSER: The doctrine doesn't apply?

THE COURT: Substantially similar doctrine?

MR. GOLDSER: Correct. Correct. The credo of the company: We believe our first responsibility is to the doctors, nurses and patients, to mothers and fathers and all others who use our products and services. In meeting their needs, everything we do must be of high quality.

Mr. Weldon needs to be present and stand for his company's credo. So I've covered the subpoena and motion to quash, as well as the evidence of other products.

MR. DAMES: The recalls on other products are

irrelevant to this case. Those other products are from different divisions. They involve different allegations. I mean, there are other different corporations. I shouldn't say different divisions. There are separate corporate entities.

For example, the Motrin and the Children's Tylenol products and the recalls to the extent that they occurred were done by separate corporate entities, and they related to a manufacturing issue, an issue that absolutely does not exist in this case.

The issue concerning recalls in other instances may, and it's some of the products mentioned in the brief, involve a potential design defect issue, issues which are not present in this case. They are separate corporate entities, separate subsidiaries of Johnson & Johnson, operated separately involving separate products and which also don't involve the regulation of the FDA over prescription medication by the company involved and the manufacturer in this case.

Now, I don't understand standard of care being somehow magically created by the statements that a company president makes about the recall of a consumer product of a separate subsidiary. It is so tenuous. This is a classic illustration of trying to raise issues concerning separate activities that may or may not be participated in by

separate corporate entities and trying to smear, in effect, trying to create a prejudicial impact upon this jury on those separate occurrences.

We would then, by the way, have to go into every separate occurrence and elicit the background and the response that the company made and the reasons for that response on each one of those things involving those different products. I ought to mention, because there is no contradiction again based on the published reports or what we heard from Mr. Goldser, there was based on the evidence to date no health impact on those recalls.

It was concern about the integrity of the product that those recalls were made on those consumer products. So we are incredibly far afield all under the guise of some sort of creation of some sort of standard of care, separate and distinct apart from any testimony by an expert who would be qualified to suggest what that standard of care is.

So I, you know, it's almost so amorphous that it's difficult at this point in time to make a better response, frankly, Your Honor. As to Mr. Weldon, he was one of the, apparently one of the few people that plaintiffs were intensely interested in who was never requested for a deposition. This litigation has been going on a very long time, and I think we have to measure the

level of interest by what was requested and what was sought.

We had many depositions in this case over a very extended period of time. There was ample discovery. Mr. Weldon was never inquired about until we come to the eve of trial so as to harass him individually and certainly the defendant shortly before the presentation of this case.

Thank you.

THE COURT: What about the substantially similar standard?

MR. DAMES: I agree. I think that is a standard that must be met, and it is a fairly high standard because the substantial similarity is one that might be not met with the same product if it involves different allegations or different claims about the deficiencies of the product. So even separate recalls on separate issues would not be necessarily substantially similar. We are --

THE COURT: What if the warning issues were substantially similar? Does that make a difference even if the products aren't?

MR. DAMES: I think it would be hard to judge a warning, the similarity of warning with very different products because we would be getting into the relevance. I mean, you know, the measurement of what is required for different products would be difficult. I don't see how you

would make that comparison, quite frankly, Your Honor.

Thank you.

MR. GOLDSER: Couple things, Your Honor. If we're going to talk about the remoteness or the rarity of tendon ruptures, we have to put it into the context of what does a company do when there is a remote or rare injury. What is that context, but what else the company does when they're faced with a remote or rare problem.

So you're right that the fact that even though they're different products, the warning standards can be similar regardless. Second, we have the same kind of problem. If they're going to introduce rarity, we need to introduce something to contravene that. If they're going to introduce Johnson & Johnson as the baby powder company, we need to do something to contravene that.

So if you're going to deny our motion to allow us to have this kind of testimony, you need to restrict Johnson & Johnson on the good things they're allowed to say about Johnson & Johnson because you're going to tie our hands and we're not able to respond to that.

MR. DAMES: I know this is under the guise of smoke out what your opponents are going to do on opening statement, and I can tell the Court, and I'm not concerned about that, quite frankly. That is not something that we will be saying. The defense of this case for us is not by

reference to the overall virtues of the company Johnson & Johnson and its subsidiaries that are involved in this case.

Clearly, I would argue the point that they are, but not in this trial. We're going to argue about the drug and how good this drug is, and that will be based upon the evidence, both from plaintiffs' experts and from our own. And in fact, you heard a fairly good presentation from Mr. Saul as well, so that's what this case will be about.

Thank you, Your Honor.

MR. GOLDSER: Just to finish that point, we're going to object to any evidence about how good this drug is for community acquired pneumonia since this is a bronchitis case. This is a bronchitis case.

MR. DAMES: That wouldn't be -- that would be incorrect, Doctor -- I mean, Your Honor. I think the doctors in this case -- perhaps you want to change careers at this point, I don't know, but the testimony in this case will not be on the part of our expert and in fact the medical records do not support bronchitis.

It was a respiratory infection, and we can argue all day long, you know, about the diagnosis, but there will be evidence to support the claims that we are making about the appropriateness of the drug for the condition suffered by the plaintiff. I think that can be best reserved

clearly for the testimony as it comes in, but the medical records don't support the claim that this is a bronchitis.

MR. GOLDSER: That's the issue that may never die in this case, so we'll leave that one for now.

THE COURT: I guess we're going to have to hear some testimony about it.

MR. GOLDSER: Last issue, the other potential causes of injury: It seems to me that the defense is going to make a big deal, as Mr. Saul said, out of the question of whether it was the steroids that caused Mr. Schedin's tendon rupture or whether his exercise subsequently was the cause of his tendon rupture, so there are two items as to which they are attributing superseding and intervening cause.

And since those are superseding intervening cause defenses and since they withdrew that defense under answer to interrogatory number 16 --

THE COURT: Let's get at that first. What is the issue there with the withdrawal of the defense through an interrogatory answer? Let me hear from the defense on that so we can clarify this issue first and foremost. I don't know that this has come up before, and I want to address this right away.

MR. DAMES: To tell you the truth, if the Court doesn't mind, I wouldn't mind addressing that at another

time. I am not prepared to address this issue today. I wasn't aware that it would come up in this context, I guess. We are contesting that there is, there is a sole proximate cause that is unrelated. There is another cause, not Levaquin, in this instance.

THE COURT: I think you have been fairly clear about that all along. That has been part of this case and the other cases as well.

MR. DAMES: That's why I'm taken a little aback by this, so if the Court would want us to submit some clarification --

THE COURT: Let's take a look at that. I want to hear your view on that because I think it raises what I think is a new issue. It might be an extremely important issue, but I just need to know what the full story is here.

MR. DAMES: Okay. We will do so, Your Honor.

THE COURT: Okay.

MR. SAUL: Your Honor, because this is a pretrial and it is an important issue, I think that I have asked eight or ten times Mr. Dames to give us the documents that Dr. Holmes relied upon that corticosteroids has caused the injury. I have not gotten them. I still have not gotten them. I was supposed to get them before the deposition.

I asked eight to ten times in writing, and I still don't have them, and I'm going to move to exclude any

testimony at the right time because I don't have them.

MR. DAMES: Well, I, I offered additional article -- it would be best I think to have a motion presented and I can articulate it better, but on the fly, the issue is Dr. Holmes's testimony concerning the impact of corticosteroids taken orally and by IV and what articles did he rely upon for it.

I have, of course, pointed out in terms of the *Daubert* motion that his own research was a good part of that because it involved research into corticosteroids, and an article that was mentioned in his deposition was given to Mr. Saul. There were other articles that were reviewed by Dr. Holmes, I was informed, on the corticosteroid issue.

I made them available -- I'm going to make them available, I should say more clearly, to Mr. Saul, but when I mentioned it over the phone, he said I'm not just interested in articles about corticosteroids that Dr. Holmes may have. What I'm interested in is what he relied upon in his deposition.

Well, with that information, I may simply be coming back to Mr. Saul and saying, you have the information. I can provide you with these additional things that he has in his possession, but we have been jockeying a little bit, I think, about what did he specifically refer to in his deposition, what does he rely

upon generically, and it's partly compounded by the fact that the deposition is not completed but will go on with the other plaintiffs.

But if there is a specific motion, I can address it, and I think that's where we are.

THE COURT: Okay. Very well.

MR. GOLDSER: I'm not sure where you left us with the motion to exclude evidence of other potential causes of injury and the corticosteroids. Remember, there are two issues. One is the corticosteroids. The other is the subsequent exercise, which clearly is a superseding intervening cause as to which they have withdrawn the defense in the interrogatory.

So is there something you want from us? That is now not clear to me.

THE COURT: Well, I need to hear from the defendants their position on this withdrawal through the interrogatory which seems to have just come up. We'll address the issue at that point after I get that information. So I'm not asking for anything from you right now.

If you wish to respond to what they come up with, that's certainly fine.

MR. GOLDSER: Okay. Thank you.

THE COURT: I've got another matter that is

scheduled here that is overdue, so I'm going to move to that in just a moment. The matters that we have sort of wrapped up here, the Court will issue a written order. Some of the issues will be addressed more briefly, but we'll do that shortly.

And the *Daubert* related motions are about to come out, together with a motion to amend and the other matters that we have discussed. Let us get these out, and then perhaps we can have a telephone conference on Monday to determine what additional time we need to argue and what additional arguments need to be done, and we can set a time then.

Is that okay? I'm going to be in Washington. That's fine. We can set up a time that works.

MR. DAMES: Mr. Robinson is offering his office for you, Your Honor.

THE COURT: That's very nice of him.

Okay. Well, let's do that. We will get these out, and then we'll -- Janet will call you, and we will set up a time that works on Monday, and then we will figure out -- I may have some time Thursday afternoon for additional arguments.

If we can't fit it in then, I think, I don't know that I have any other choice other than have some arguments on Saturday morning, which works fine for the Court, so

that we get them all wrapped up before we start on Monday morning.

MR. GOLDSER: That's fine. Is Holly on maternity leave?

THE COURT: About an hour and a half ago she was still here, but she has got to be getting close, and I think she's ready for it, too.

MR. GOLDSER: Please wish her the best from all of us.

THE COURT: We will. Okay. Very well. We will be in recess. Thank you very much. We will be back in about four minutes.

(Court was adjourned.)

* * *

I, Kristine Mousseau, certify that the foregoing is a correct transcript from the record of proceedings in the above-entitled matter.

Certified by: s/Kristine Mousseau
Kristine Mousseau, CRR-RPR